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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,599	10/23/2001	Lino Tavares	208.1002US	8566

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EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/045,599	TAVARES ET AL.	
	Examin r	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE f this communication appears n the c ver sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,22-40,42-44 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,22-40,42-44 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18 and 22 - 47, drawn to a method of treating benign prostatic hypertrophy transdermally with terazosin, classified in class 424, subclass 449.

II. Claims 19 – 21 and 48, drawn to a method of treating side effects transdermally, classified in class 424, subclass 449.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to completely different mechanisms and uses for the device of the invention. Group I is drawn to a treatment method for benign prostatic hypertrophy, while group II is drawn to the treatment of unspecified side effects.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: in claims 35 – 38, 41 and 46,

- The backing layer material:
    a. A flexible material
    b. An inflexible material
    c. An aluminum foil
- Polymeric matrix:
    a. Rubber

b. A rubber like synthetic homo-, co-, or block polymer

c. A urethane

d. Silicone

e. Copolymer of 2-ethylhexyl acrylate

f. Vinyl acetate and acrylic acid

1. Softening agent

a. Dodecanol

b. Undecanol

c. Octanol

d. Glycol and glycanol

e. Medium chain triglyceride of the caprylic/capric acids of coconut oil

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 25 and 28 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant has elected group I without traverse and by amendment canceled claims 19-21, 26, 41, 45, 46 and 48. The pending claims are now: 1-18, 22-25, 27-40, 42-44, and 47. The following is the prosecution of the pending claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-18, 22-25, 27-40, 42-44, and 47 rejected under 35 U.S.C. 103(a) as being unpatentable over Ma et al (USPN 5,843,472) in view of Audett et al (USPN 5,879,701). Claims 1-18 are drawn to a method of treating benign prostatic hypertrophy in a human patient by administering terazosin transdermally. The claims recite the proper dosage regimen for the transdermal administration. The remaining claims are drawn to the transdermal device used in the method of claims 1-18. The device comprises an impermeable yet flexible backing layer, and a removable release liner. The polymeric matrix is a pressure sensitive adhesive with a silicone substrate. The device contains solvents and other well-known components.

Ma et al discloses a transdermal device useful in the treatment of benign prostatic hypertrophy (BPH). The device delivers basic drugs such as tamsulosin transdermally in order to treat benign prostatic hypertrophy. The device comprises an impermeable flexible backing layer and a release liner. The device is a pressure sensitive adhesive with a polymeric matrix. The matrix uses silicone as a polymeric carrier and contains various glycols. Solvents used for the device include ethanol, and oleic acid solvents (Abstract; col. 6,lin. 29 – col. 8, lin. 58; claims).

What the reference is lacking is a disclosure of terazosin as the active agent. Audett et al discloses a transdermal formulation and device comprising a polymeric matrix, an impermeable yet flexible backing layer, a release liner and terazosin as an active basic drug ingredient (Abstract; col. 5, lin. 50 – 60; col. 6, lin. 63 – col. 8, lin. 50; claims). Since the two compositions

and devices contain similar if not identical components, and structures, and are used for similar purposes, it would have been obvious to a skilled artisan to substitute the terazosin of Audett into the delivery device of Ma.

The claims are drawn to specific release profiles and dosage regimens in order to treat the BPH. The references and their combination do not recite the identical treatment regimen, yet this determination would be within the level of ordinary skill in the art. The claims also are drawn to specific concentrations of the particular components. These concentrations too can be determined through routine experimentation, by a skilled artisan. The general combination of components is presented in the art. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

4. Further claims 7, 8, 17, 18, 23, 24 and 34 recite that the transdermal has a particular in vitro behavior as determined by a Valia-Chien. It is the position for the examiner that these limitations are irrelevant to the patentability of the device and methods of use. These properties would be inherent to any identical transdermal comprising similar concentration and proportions made from similar and/or identical components. These limitations do not impart patentability on

the invention by simply recited the results of diagnostic test which can be preformed by a skilled artisan of ordinary skill. It is the position of the examiner that given the combination of references presented, a skilled artisan would attain similar if not identical in vitro results from the same test.

5. With regard to claims 39 and 40, which recite particular solvents, it is the position of the examiner that these limitations do not impart patentability o n the invention. The mere selection of species is well within the level of skill in the art. Barring a showing of criticality and unexpected results with the particular solvents, the limitations are deemed non-critical to the patentability of the invention.

6. With this in mind a skilled artisan would have been motivated to combine the teachings and suggestions of the art. A skilled artisan would have been motivated to combine the terazosin suggested by Audett with the transdermal formula and device of Ma in order to treat benign prostatic hypertrophy. A skilled artisan would have been motivated to make this combination since both transdermal formulations and devices comprise similar components and were used for the delivery of drugs and for the treatment of similar ailments. From this combination a skilled artisan would be able to modify and optimize the concentrations of the active components in order to better deliver the pharmaceutical agents. A skilled artisan would be able to optimize the release and permeation of the drugs in to the skin. A skilled artisan would have expected from the combination transdermal device useful in the treatment of benign prostatic hypertrophy.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young
June 12, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600